NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANSSEN, L.P., JANSSEN PHARMACEUTICA N.V., and ORTHO-MCNEIL NEUROLOGIES, INC., Plaintiffs, v. BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC., Defendants.	Civil Action No. 07-1515 (JAP)
JANSSEN, L.P., JANSSEN PHARMACEUTICA N.V., and ORTHO-MCNEIL NEUROLOGIES, INC., Plaintiffs, v. KV PHARMACEUTICAL COMPANY, Defendant.	Civil Action Nos. 07-5982 & 08-3012 (JAP)
JANSSEN, L.P., JANSSEN PHARMACEUTICA N.V., and ORTHO-MCNEIL NEUROLOGIES, INC., Plaintiffs, v. SANDOZ, INC. Defendant.	Civil Action No. 08-2892 (JAP)

OPINION

PISANO, District Judge.

Presently before the Court in this patent infringement case is the parties' request for claim construction. Plaintiffs, Janssen, L.P., Janssen Pharmaceutica N.V. and Ortho-McNeil Neurologics, Inc. (collectively "Plaintiffs"), have brought this action against Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., KV Pharmaceutical Company, and Sandoz, Inc. ("Barr," "KV," and "Sandoz," respectively, and "Defendants" collectively) claiming that Defendants infringed on Plaintiffs' patent, United States Patent No. 7,160,559 (the "'559 Patent"). This patent claims a controlled release formulation of galantamine hydrobromide, which is a drug used to treat Alzheimer's disease. Plaintiffs market this drug under the trade name RAZADYNE-ER®.

The instant action was filed on March 30, 2007. On September 29, 2008, Plaintiffs filed an Opening Claim Construction Brief. Defendants subsequently fully briefed the issue of the construction of the disputed claim terms. The Court held a *Markman* hearing on January 12, 2009. This Opinion addresses the proper construction of the disputed claim terms.

I. Standards for Claim Construction

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370 (1996). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim

construction is a matter of law, *Markman v. Westview Instrs., Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370 (1996), therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d 1312 (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention--the inventor's lexicography--must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decision making process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir.1998)).

In the process of determining the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314. While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."

II. The Disputed Claim Terms

The parties have submitted a Joint Claim Construction Statement in which they have identified three disputed claim terms. The Court will address each of these in turn.

1. "controlled release formulation[1]"

[1]In their joint claim construction chart, the parties indicated that the phrase "controlled release formulation" was in dispute. Both Plaintiffs and KV provided proposed constructions, however, neither Barr nor Sandoz provided their own constructions. During oral argument, the parties agreed that the dispute revolves around the meaning of the term "formulation" and

This disputed phrase appears in claim 1 of the '559 Patent. Plaintiffs' proposed construction for this phrase is as follows: "a pharmaceutical composition for oral administration in which the release profile of the active ingredient includes a component that is not released immediately." KV, on the other hand, argues that the term should be construed as: a "component of a dosage form that provides a release of an active ingredient, which is altered from the release provided by an immediate release formulation."

The difference between the two suggested constructions is whether "formulation" refers to the entire dosage form administered to the patient or whether it refers to only a portion of the dosage form. Plaintiffs claim that formulation "encompasses the dosage form as a whole that is administered to the patient," whereas KV argues that the term "formulation" "refers to part of a full dosage form, such as a pellet in a capsule (the pellet is the formulation and the capsule is the dosage form)." Pl.'s Opening Brief at 10 ("Pl's Brief"); KV's Opening Brief at 11 ("KV's Brief").

In support of its proposed construction, Plaintiffs first look to the plain meaning of the term "formulation". According to Plaintiffs, formulation "refers to that which is formulated" meaning the pharmaceutical composition in its entirety, rather than a portion of the dosage form. Pl.'s Brief at 10-11. However, the ordinary meaning does not necessarily control if the specification provides otherwise. *Phillips*, 415 F.3d at 1315-17. Here, the specification states: "Dosage forms comprising a therapeutically effective amount of said controlled release formulations can be administered orally to a patient once daily." '559 patent at 2:46-48. As

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not the entire phrase "controlled release formulation." Tr. p. 19:18-20:19. As such, the Court focuses its analysis on the term "formulation" and not the entire phrase.

such, the patent itself makes clear that "dosage form" does not equate with "formulation," rather the controlled release formulation is a component of the dosage form.

Defendants' construction is further bolstered by the prosecution history. For instance, application claim 16, in the initial claims submitted to the PTO, states: "A dosage form comprising a therapeutically effective amount of the controlled release formulation of any claims 1 to 15." Decl. Lynn Ulrich, Def.'s Joint Ex., Tab 18, June 21, 2001 Prelim. Am. at 8, App. Claim 16. It would be redundant if formulation meant dosage form. As such, Plaintiffs must have contemplated a difference between the terms "dosage form" and "formulation" in their initial application.

Furthermore, the claims themselves support Defendants' construction. Specifically, KV cites to claim 15 which states: "[a] formulation according to [c]laim 1, wherein the particles are filled in a hard-gelatin capsule." '559 patent 16:4-5. KV argues that formulation cannot be the entire drug product, as Plaintiffs claim, because claim 15 requires the formulation to be filled into the capsule, i.e. the finished drug product. KV's Brief at 12. According to KV, if "formulation" is construed according to Plaintiffs' construction it would have two contrary meanings - particles to be filled into a capsule and a finished drug product. *Id.* KV argues that since claims must be construed consistently throughout the patent, Plaintiffs' interpretation cannot stand. *Phillips*, 415 F.3d at 1314.

On the other hand, Plaintiffs contend that several claims support their construction. For instance, they argue that the use of the term formulation in claim 11 - "[a] formulation according to claim 1 providing a mean maximum plasma concentration of galantamine from

10 to 60 ng/ml and a mean minimum plasma concentration from 3 to 15 ng/ml after repeated administration every day through steady-state conditions," '559 patent at 14:52-6 - must refer to the entire dosage because steady-state plasma concentrations cannot stem from only a part of the entire dosage. Similarly, Plaintiffs assert that claim 13 refers to the entire dosage form. Claim 13 provides: "comprising administering to a human in need of such treatment, a therapeutically effective amount of galantamine in a controlled release formulation as claimed in claim 1, said amount being sufficient to alleviate said Alzheimer's dementia, but insufficient to cause said adverse effects." '559 patent at 14:65-16:6. Plaintiffs argue that Alzheimer's disease cannot be treated through the administration of only a portion of the drug, so formulation must refer to the entire dosage form. However, the Court is not persuaded by this argument because Plaintiffs' interpretation of claims 11 and 13 directly contradicts the plain language of claim 15 as well as the specification and the prosecution history.

Considering the plain language of claim 1 as well as the specification of the '559 Patent, and the patent prosecution history, the Court shall construe "controlled release formulation" consistent with KV's proposed construction as follows: "component of a dosage form that provides a release of an active ingredient, which is altered from the release provided by an immediate release formulation."

2. "and wherein the formulation further comprises a topcoat comprising galantamine and water-soluble polymer"

The main dispute in this phrase centers around the term "topcoat". Topcoat appears in claims 1 and 12 of the patent. Plaintiffs' position is that the topcoat need not be the

outermost layer but may be any layer that is not covered by a release rate controlling membrane. On the other hand, the Defendants argue that the topcoat must be the outermost layer. Specifically, Plaintiff's proposed construction is as follows: "The drug product includes one or more layers of coating material that includes galantamine and a water-soluble polymer and that are not covered by a release rate controlling membrane, such that the formulation is capable of releasing some galantamine in a manner consistent with the release profile set forth below." Each of the Defendants offered their own construction of the phrase as follows:

KV: "The component of a dosage form that provides for the altered release additionally has an outmost coating comprising galantamine and water-soluble polymer."

Barr: "And wherein the formulation as previously defined in claim 1 also has an additional, outermost coating comprising galantamine and water-soluble polymer."

Sandoz: "The particles previously defined in claim 1 have an additional, outermost coating comprising galantamine and water-soluble polymer."

The plain meaning of "topcoat" supports Defendants' position that it is the outermost layer. The Court first turns to the dictionary definition of "topcoat". The Federal Circuit has approved the use of the dictionary when fleshing out a term's plain meaning as long as the definition does not contradict any specific meaning of the word in the patent. *Phillips*, 415 F.3d at 1322. In Webster's Dictionary, "topcoat" is defined as "an overcoat" as in a "protective coating". *Merriam-Webster*, http://www.merriam-webster.com/dictionary/topcoat (site last visited Feb. 6, 2009). Since none of the parties have argued that "topcoat" has a specific meaning in the patent itself, the Court finds that the plain meaning

supports Defendants' construction.

Furthermore, the language of dependent claim 12 confirms that topcoat is the outermost layer. Specifically, claim 12 provides: "A process of preparing a formulation according to claim 1 comprising admixing galantamine hydrobromide (1:1) with a water soluble film forming polymer and coating onto inert spheres to form a drug core, optionally applying a seal coat to the drug core, applying the release rate controlling membrane, and thereafter applying a topcoat comprising galantamine and a water-soluble polymer." '559 patent at 14:57-64. This claim describes a multi-stage layering process with the "topcoat comprising galantamine and a water-soluble polymer" being the last coat applied; thus rendering it the outermost coat. *Id.*

Moreover, the patent specification is consistent with the ordinary meaning discussed above and directs the topcoat layer to be applied on top of the controlled release particles. The specification states that "part of the galantamine is present in an immediate release form ... or as a topcoat on the controlled release formulation." '559 patent at 2:50-54. Furthermore, Example 5 provides "the controlled release membrane coated spheres were sprayed with the drug topcoat solution. ... The topcoated spheres were [then] filled into hard-gelatin capsules." '559 patent at 12:58-65. According to this example, there is a final drug layer on top of the controlled release membrane, thus the topcoat is the outermost layer. Plaintiffs' contention that the topcoat need not be the outermost layer, is inconsistent with this example.

The patent prosecution history also supports the Defendants' constructions. During

the patent prosecution, Plaintiffs amended application claim 10 (now issued claim 1) to add a topcoat limitation to overcome an obviousness rejection based on U.S. Patent No. 5,576,022 ("Yang Patent"). Defs.' Joint Exhibit 2, Tab 82, Oct. 21, 2005 Am. at 3. The Yang Patent "discloses a controlled release formulation that comprises an immediate release core that comprises nonpareil seeds, tacrine and a binding agent, a sealing layer or sustained release layer over the immediate release pellets.[2]" The Yang Patent contains a mix of immediate release and controlled release particles in which the controlled release particles are akin to immediate release particles covered by a sustaining layer. In order to distinguish its controlled release particles from Yang's, Plaintiffs amended their initial application to require " the controlled release formulation of the present invention [to] further comprise[] an immediate release topcoat of galantamine and water-soluble polymer which provides the specified release rate of galantamine from the formulation which is not taught or suggested by Yang et al." *Id.* at 7. Based on this, the Patent Examiner stated that Plaintiffs' "invention is distinguished over the prior art by having a topcoat comprising galantamine and water-soluble polymer disposed over the water-insoluble polymer membrane." Defs.' Joint Exhibit 2, Tab 110, at 2-3. The PTO issued Plaintiffs' patent because it understood that the topcoat was the outerlayer over the controlled release particle. Plaintiffs cannot now alter their claims to recapture through claim interpretation what they previously disclaimed during prosecution. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("the doctrine of prosecution

[2]"The 'sustaining layer' described in Yang serves a similar function as the 'release-rate controlling membrane coating' in the particles of the '559 patent. (Ex. J, Yang, col. 3, ll. 56-60 (noting that one of the components of the 'sustaining layer' works as 'a diffusion barrier for the [API] and controls its release rate'.))" Sandoz Opening Brief fn. 12 at 23.

disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.")

Finally, the extrinsic evidence confirms Defendants' construction. Specifically, several of the patent's inventors testified that they understood topcoat to be the outermost coating. For instance, in response to the following question: "Is it your understanding that what has been referred to here is that the outermost coat if the formulation has to have galantamine and water soluble polymer," Inventor Marc De Weer responded: "To my understanding, yes." Barr Opening Brief, Ex. H, De Weer Dep. Tr. at 54:22-55:4. Similarly, when asked about his understanding of topcoat, Inventor Paul McGee testified: "We were thinking of top[]coat as being on the outside." Barr Opening Brief, Ex. I, McGee Dep. Tr. at 193:11-14.

Considering the plain language of claims 1 and 12 as well as the specification of the '559 Patent, the patent prosecution history, and relevant extrinsic evidence, the Court shall construe "topcoat" consistent with KV's proposed construction as follows: "the component of a dosage form that provides for the altered release additionally has an outmost coating comprising galantamine and water-soluble polymer.[3]"

3. "and wherein the formulation is capable of releasing ..."

This phrase appears in claim 1 of the patent. The dispute also, centers around the term "formulation". Plaintiffs' proposed construction is as follows: "The controlled release

[3]The Court selects KV's construction out of the proposals submitted by the Defendants because it also includes the definition of formulation that was previously adopted by the Court.

formulation releases 20-40% of the active ingredient, galantamine hydrobromide, in the formulation within the first hour and releases more than 80% of the active ingredient, galantamine hydrobromide, within ten hours. Release of the formulation is measured in USP buffer pH 6.8 at 37°C in a paddle apparatus operating at 50 rpm." Each of the Defendants offered their own construction of the phrase:

KV: "The component of a dosage form that provides for the altered release and that has a topcoat of galantamine and water-soluble polymer releases."

Barr: "And wherein the formulation as previously defined in claim 1 releases."

Sandoz: "The particles previously defined in claim 1 release the galantamine hydrobromide as set forth in the claim."

Because the main focus of this dispute centers around the term "formulation," the Court adopts KV's proposed construction as it is most consistent with the construction of formulation discussed above.

III. Conclusion

For the reasons set forth above, the terms at issue will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: February 19, 2009